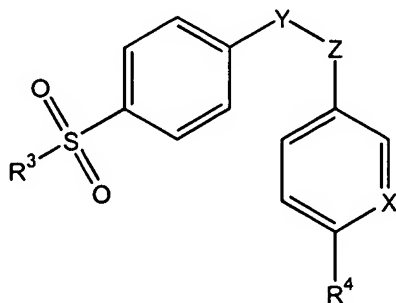


## II. LISTING OF CLAIMS

This listing of claims will replace all prior versions, and listings, of the claims in the application:

1. (Original) An orally deliverable pharmaceutical composition comprising
  - (a) a drug of low water solubility;
  - (b) a pharmaceutically acceptable solvent liquid; and
  - (c) a turbidity-decreasing polymer;wherein at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid, and wherein said polymer is present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid.
2. (Original) The composition of Claim 1 wherein the drug is present in a therapeutically effective amount.
3. (Original) The composition of Claim 1 wherein the drug is present in a total amount of about 1% to about 75% by weight of the composition.
4. (Original) The composition of Claim 1 wherein at least about 15% of the drug is present in the solvent liquid in dissolved or solubilized form.
5. (Original) The composition of Claim 1 wherein substantially all of the drug is present in the solvent liquid in dissolved or solubilized form.
6. (Original) The composition of Claim 1 wherein the drug is a selective cyclooxygenase-2 inhibitory drug.
7. (Original) The composition of Claim 6 wherein the selective cyclooxygenase-2 inhibitory drug is a compound having the formula



where R<sup>3</sup> is a methyl or amino group, R<sup>4</sup> is hydrogen or a C<sub>1-4</sub> alkyl or alkoxy group, X is N or CR<sup>5</sup> where R<sup>5</sup> is hydrogen or halogen, and Y and Z are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; or a prodrug of such a compound.

8. (Original) The composition of Claim 7 wherein the five- to six-membered ring is selected from cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.
9. (Original) The composition of Claim 6 wherein the selective cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
10. (Original) The composition of Claim 9 wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib.
11. (Original) The composition of Claim 10 that comprises one or more dose units each comprising about 10 mg to about 1000 mg of celecoxib.
12. (Original) The composition of Claim 10 that comprises one or more dose units each comprising about 50 mg to about 400 mg of celecoxib.
13. (Original) The composition of Claim 9 wherein the drug is valdecoxib.
14. (Original) The composition of Claim 1 wherein the turbidity-decreasing polymer is selected from the group consisting of polyvinylpyrrolidone and cellulosic polymers.
15. (Original) The composition of Claim 1 wherein the turbidity-decreasing polymer is a cellulosic polymer selected from the group consisting of sodium carboxymethylcellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose and ethylcellulose.
16. (Original) The composition of Claim 15 wherein the cellulosic polymer is hydroxypropylmethylcellulose.

17. (Original) The composition of Claim 16 wherein the hydroxypropylmethylcellulose has about 15% to about 35% methoxyl substitution and about 3% to about 15% hydroxypropoxyl substitution.
- ~~19-18.~~ 18. (Currently amended) The composition of Claim 16 wherein the hydroxypropylmethylcellulose has about 19% to about 30% methoxyl substitution and about 4% to about 12% hydroxypropoxyl substitution.
- ~~20-19.~~ 19. (Currently amended) The composition of Claim 16 wherein the hydroxypropylmethylcellulose has about 19% to about 24% methoxyl substitution and about 7% to about 12% hydroxypropoxyl substitution.
- ~~21-20.~~ 20. (Currently amended) The composition of Claim 6 further comprising a vasomodulator, wherein the selective cyclooxygenase-2 inhibitory drug and the vasomodulator are present in total and relative amounts effective to relieve pain in headache or migraine.
- ~~22-21.~~ 21. (Currently amended) The composition of Claim 6 further comprising an alkylxanthine compound, wherein the selective cyclooxygenase-2 inhibitory drug and the alkylxanthine compound are present in total and relative amounts effective to relieve pain in headache or migraine.
- ~~23-22.~~ 22. (Currently amended) The composition of Claim 21 22 where in the alkylxanthine compound is selected from the group consisting of caffeine, theophylline and theobromine.
- ~~24-23.~~ 23. (Currently amended) The composition of Claim 21 22 wherein the alkylxanthine compound is caffeine.
- ~~25-24.~~ 24. (Currently amended) The composition of Claim 1 wherein the turbidity-decreasing polymer is present in the solvent liquid in an amount of about 1% to about 20% by weight of the solvent liquid.
- ~~26-25.~~ 25. (Currently amended) The composition of Claim 1 wherein the turbidity-decreasing polymer is present in the solvent liquid in an amount of about 1% to about 15% by weight of the solvent liquid.
- ~~27-26.~~ 26. (Currently amended) The composition of Claim 1 that is an imbibable liquid.

~~28-27.~~ (Currently amended) The composition of Claim 1 further comprising a water-soluble capsule wall wherein the drug and solvent liquid are encapsulated.

~~29-28.~~ (Currently amended) The composition of Claim ~~27~~ 28 wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 5% to about 100% by weight of the wall.

~~30-29.~~ (Currently amended) The composition of Claim ~~27~~ 28 wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 15% to about 100% by weight of the wall.

~~31-30.~~ (Currently amended) The composition of Claim 1 wherein the solvent liquid comprises a solvent selected from the group consisting of pharmaceutically acceptable glycols and glycol ethers.

~~32-31.~~ (Currently amended) The composition of Claim ~~30~~ 31 wherein the solvent is polyethylene glycol.

~~33-32.~~ (Currently amended) The composition of Claim ~~30~~ 31 wherein the polyethylene glycol has an average molecular weight of about 100 to about 10,000.

~~34-33.~~ (Currently amended) The composition of Claim ~~30~~ 31 wherein the polyethylene glycol has an average molecular weight of about 100 to about 1,000.

~~35-34.~~ (Currently amended) The composition of Claim ~~30~~ 31 wherein the polyethylene glycol has an average molecular weight of about 375 to about 450.

~~36-35.~~ (Currently amended) The composition of Claim ~~30~~ 31 wherein the polyethylene glycol is of liquid grade.

~~37-36.~~ (Currently amended) An orally deliverable pharmaceutical composition comprising

- (a) a drug of low water solubility;
- (b) a pharmaceutically acceptable solvent liquid; and
- (c) a cellulosic polymer;

wherein at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid, and wherein said cellulosic polymer is present in an amount

sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid.

~~38-37.~~ (Currently amended) The composition of Claim ~~36~~ ~~37~~ wherein the drug is present in a therapeutically effective amount.

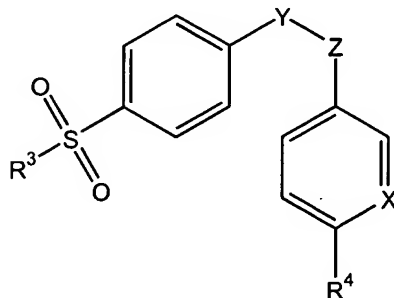
~~39-38.~~ (Currently amended) The composition of Claim ~~36~~ ~~37~~ wherein the drug is present in a total amount of about 1% to about 75% by weight of the composition.

~~40-39.~~ (Currently amended) The composition of Claim ~~36~~ ~~37~~ wherein at least about 15% of the drug is present in the solvent liquid in dissolved or solubilized form.

~~41-40.~~ (Currently amended) The composition of Claim ~~36~~ ~~37~~ wherein substantially all of the drug is present in the solvent liquid in dissolved or solubilized form.

~~42-41.~~ (Currently amended) The composition of Claim ~~36~~ ~~37~~ wherein the drug is a selective cyclooxygenase-2 inhibitory drug.

~~43-42.~~ (Currently amended) The composition of Claim ~~41~~ ~~42~~ wherein the selective cyclooxygenase-2 inhibitory drug is a compound having the formula



where  $R^3$  is a methyl or amino group,  $R^4$  is hydrogen or a  $C_{1-4}$  alkyl or alkoxy group, X is N or  $CR^5$  where  $R^5$  is hydrogen or halogen, and Y and Z are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; or a prodrug of such a compound.

~~44-43.~~ (Currently amended) The composition of Claim ~~42~~ ~~43~~ wherein the five- to six-membered ring is selected from cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.

~~45-44.~~ (Currently amended) The composition of Claim ~~41~~ ~~42~~ wherein the selective

- cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
- ~~46:~~ 45. (Currently amended) The composition of Claim 44 ~~45~~ wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib.
- ~~47:~~ 46. (Currently amended) The composition of Claim 45 ~~46~~ that comprises one or more dose units each comprising about 10 mg to about 1000 mg of celecoxib.
- ~~48:~~ 47. (Currently amended) The composition of Claim 45 ~~46~~ that comprises one or more dose units each comprising about 50 mg to about 400 mg of celecoxib.
- ~~50:~~ 48. (Currently amended) The composition of Claim 43 wherein the drug is valdecoxib.
- ~~51:~~ 49. (Currently amended) The composition of Claim 36 ~~37~~ wherein the cellulosic polymer is selected from the group consisting of sodium carboxymethylcellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose, and ethylcellulose.
- ~~52:~~ 50. (Currently amended) The composition of Claim 36 ~~37~~ wherein the cellulosic polymer is hydroxypropylmethylcellulose.
- ~~53:~~ 51. (Currently amended) The composition of Claim 50 ~~52~~ wherein the hydroxypropylmethylcellulose has about 15% to about 35% methoxyl substitution and about 3% to about 15% hydroxypropoxyl substitution.
- ~~54:~~ 52. (Currently amended) The composition of Claim 50 ~~52~~ wherein the hydroxypropylmethylcellulose has about 19% to about 30% methoxyl substitution and about 4% to about 12% hydroxypropoxyl substitution.
- ~~55:~~ 53. (Currently amended) The composition of Claim 50 ~~52~~ wherein the hydroxypropylmethylcellulose has about 19% to about 24% methoxyl substitution and about 7% to about 12% hydroxypropoxyl substitution.

- ~~56:~~ 54. (Currently amended) The composition of Claim ~~41~~ 42 further comprising a vasomodulator, wherein the selective cyclooxygenase-2 inhibitory drug and the vasomodulator are present in total and relative amounts effective to relieve pain in headache or migraine.
- ~~57:~~ 55. (Currently amended) The composition of Claim ~~41~~ 42 further comprising an alkylxanthine compound, wherein the selective cyclooxygenase-2 inhibitory drug and the alkylxanthine compound are present in total and relative amounts effective to relieve pain in headache or migraine.
- ~~58:~~ 56. (Currently amended) The composition of Claim ~~55~~ 57 wherein the alkylxanthine compound is selected from the group consisting of caffeine, theophylline and theobromine.
- ~~59:~~ 57. (Currently amended) The composition of Claim ~~56~~ 58 wherein the alkylxanthine compound is caffeine.
- ~~60:~~ 58. (Currently amended) The composition of Claim ~~36~~ 37 wherein the cellulosic polymer is present in the solvent liquid in an amount of about 1% to about 20% by weight of the solvent liquid.
- ~~61:~~ 59. (Currently amended) The composition of Claim ~~36~~ 37 wherein the cellulosic polymer is present in the solvent liquid in an amount of about 1% to about 15% by weight of the solvent liquid.
- ~~62:~~ 60. (Currently amended) The composition of Claim ~~36~~ 37 that is an imbibable liquid.
- ~~63:~~ 61. (Currently amended) The composition of Claim ~~36~~ 37 further comprising a water-soluble capsule wall wherein the drug and solvent liquid are encapsulated.
- ~~64:~~ 62. (Currently amended) The composition of Claim ~~61~~ wherein the cellulosic polymer is present in the capsule wall in an amount of about 5% to about 100% by weight of the wall.
- ~~65:~~ 63. (Currently amended) The composition of Claim ~~61~~ 63 wherein the cellulosic polymer is present in the capsule wall in an amount of about 15% to about 100% by weight of the wall.

- ~~66:~~ 64. (Currently amended) The composition of Claim 36 ~~37~~ wherein the solvent liquid comprises a solvent selected from the group consisting of pharmaceutically acceptable glycols and glycol ethers.
- ~~67:~~ 65. (Currently amended) The composition of Claim 64 ~~66~~ wherein the solvent is polyethylene glycol.
- ~~68:~~ 66. (Currently amended) The composition of Claim 65 ~~67~~ wherein the polyethylene glycol has an average molecular weight of about 100 to about 10,000.
- ~~69:~~ 67. (Currently amended) The composition of Claim 65 ~~67~~ wherein the polyethylene glycol has an average molecular weight of about 100 to about 1,000.
- ~~70:~~ 68. (Currently amended) The composition of Claim 65 ~~67~~ wherein the polyethylene glycol has an average molecular weight of about 375 to about 450.
- ~~71:~~ 69. (Currently amended) The composition of Claim 65 ~~67~~ wherein the polyethylene glycol is of liquid grade.
- ~~72:~~ 70. (Currently amended) An orally deliverable pharmaceutical composition comprising a drug of low water solubility in a high energy phase together with one or more pharmaceutically acceptable excipients, encapsulated within a capsule wall that comprises a turbidity-decreasing polymer in an amount effective to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid.
- ~~73:~~ 71. (Currently amended) The composition of Claim 70 ~~72~~ wherein the drug is a selective cyclooxygenase-2 inhibitory drug.
- ~~74:~~ 72. (Currently amended) The composition of Claim 71 ~~73~~ wherein the selective cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
- ~~75:~~ 73. (Currently amended) The composition of Claim 72 ~~74~~ wherein the selective



cyclooxygenase-2 inhibitory drug is celecoxib.

~~76.~~ 74. (Currently amended) The composition of Claim 70 ~~72~~ wherein said high energy phase is an amorphous phase of the drug.

~~77.~~ 75. (Currently amended) The composition of Claim 70 ~~72~~ wherein said high energy phase is a salt of an acid or base form of the drug.

~~78.~~ 76. (Currently amended) The composition of Claim 70 ~~72~~ wherein the turbidity-decreasing polymer is a cellulosic polymer.

~~79.~~ 77. (Currently amended) The composition of Claim 76 ~~78~~ wherein the cellulosic polymer is selected from the group consisting of sodium carboxymethylcellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose, and ethylcellulose.

~~80.~~ 78. (Currently amended) The composition of Claim 76 ~~78~~ wherein the cellulosic polymer is hydroxypropylmethylcellulose.

~~81.~~ 79. (Currently amended) The composition of Claim 78 ~~80~~ wherein the hydroxypropylmethylcellulose has about 15% to about 35% methoxyl substitution and about 3% to about 15% hydroxypropoxyl substitution.

~~82.~~ 80. (Currently amended) The composition of Claim 78 ~~80~~ wherein the hydroxypropylmethylcellulose has about 19% to about 30% methoxyl substitution and about 4% to about 12% hydroxypropoxyl substitution.

~~83.~~ 81. (Currently amended) The composition of Claim 78 ~~80~~ wherein the hydroxypropylmethylcellulose has about 19% to about 24% methoxyl substitution and about 7% to about 12% hydroxypropoxyl substitution.

~~84.~~ 82. (Currently amended) The composition of Claim 70 ~~72~~ wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 5% to about 100% by weight of the wall.

~~85.~~ 83. (Currently amended) The composition of Claim 70 ~~72~~ wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 15% to about 100% by weight of the wall.

- ~~86:~~ 84. (Currently amended) A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 6, Claim 41 ~~42~~, or Claim 71 ~~73~~.
- ~~87:~~ 85. (Currently amended) A method of analgesia comprising orally administering, to a subject in need of analgesia, an effective pain-relieving amount of a composition of Claim 6, Claim 41 ~~42~~, or Claim 71 ~~73~~.
- ~~88:~~ 86. (Currently amended) The method of Claim 85 ~~87~~ wherein the subject suffers from headache or migraine and wherein there is further orally administered to the subject a vasomodulator, the selective cyclooxygenase-2 inhibitory drug and the vasomodulator being administered in total and relative amounts effective to relieve pain in the headache or migraine.
- ~~89:~~ 87. (Currently amended) The method of Claim 86 ~~88~~ wherein the vasomodulator is co-formulated with the selective cyclooxygenase-2 inhibitory drug.
- ~~90:~~ 88. (Currently amended) The method of Claim 85 ~~87~~ wherein the subject suffers from headache or migraine and wherein there is further orally administered to the subject an alkylxanthine compound, the selective cyclooxygenase-2 inhibitory drug and the alkylxanthine compound being administered in total and relative amounts effective to relieve pain in the headache or migraine.
- ~~91:~~ 89. (Currently amended) The method of Claim 88 ~~90~~ wherein the alkylxanthine compound is co-formulated with the selective cyclooxygenase-2 inhibitory drug.
- ~~92:~~ 90. (Currently amended) The method of Claim 89 ~~91~~ wherein the alkylxanthine compound is selected from the group consisting of caffeine, theophylline, and theobromine.
- ~~93:~~ 91. (Currently amended) The method of Claim 89 ~~91~~ wherein the alkylxanthine compound is caffeine.